UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MITSUBISHI CHEMICAL CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, ENCYSIVE PHARMACEUTICALS INC., GLAXO GROUP LIMITED AND SMITHKLINE BEECHAM PLC, Plaintiffs, v. BARR LABORATORIES, INC. AND PLIVA-HRVATSKA D.O.O, Defendants.	Civil Action No. 1:07-CV-11614-JGK **Electronically Filed** **Oral Argument Requested**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO MOTION OF GLAXO GROUP LTD AND SMITHKLINE BEECHAM PLC FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

Defendants, Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o. (collectively "Barr"), oppose the motion of Glaxo Group Limited ("GGL") and SmithKline Beecham plc ("SKB") (collectively "GSK Plaintiffs") for leave to file a Second Amended Complaint ("Motion") to add SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("SKB Corp.") as a plaintiff. Plaintiffs Mitsubishi Chemical Corporation ("Mitsubishi Chemical"), Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe"), and Encysive Pharmaceuticals Inc. ("Encysive") did not join the GSK Plaintiffs' Motion.

I. SUMMARY OF ARGUMENT

The GSK Plaintiffs' Motion should be denied because (1) their proposed amendment is futile, (2) their proposed amendment would prejudice Barr, and (3) they failed to cure their deficiency by previous amendment.

The amendment is futile because SKB Corp. lacked standing at the time the December 28, 2007 Complaint ("Complaint") was filed (and even at the time the First Amended Complaint was filed), and standing defects cannot be cured retroactively. The amendment would prejudice Barr because adding SKB Corp. as a plaintiff likely would impact such issues as the possibility of injunctive relief and potential damages if Mitsubishi Chemical's patent were not invalidated. Finally, the GSK Plaintiffs had ample opportunity after learning about Barr's Abbreviated New Drug Application ("ANDA") to ensure that SKB Corp. possessed appropriate rights to ensure their standing, yet failed to do so twice and should not now be allowed a third bite at the apple. The GSK Plaintiffs are well-heeled, sophisticated corporations that should have appropriately structured their relative rights with SKB Corp. – or fixed them – before filing this lawsuit if they wanted SKB Corp. to be a party. Now, the GSK Plaintiffs must live with the

consequences of their strategic choices. If the current plaintiffs wish to litigate with SKB Corp. as a party, it cannot be in this suit. The GSK Plaintiffs' Motion should be denied.

II. BACKGROUND

This suit stems from an ANDA filing that seeks to market a low-cost version of argatroban. Argatroban is an anticoagulant drug. The patent on the argatroban compound has expired, but Encysive has listed U.S. Patent No. 5,214,052 (the "'052 patent") with the Food and Drug Administration ("FDA") as covering the currently approved argatroban product. The '052 patent is directed to a pharmaceutical composition containing argatroban in a specific solution. Barr Laboratories, Inc. submitted an ANDA to the FDA related to a generic argatroban product. On November 16, 2007, Barr Laboratories, Inc. sent a letter notifying Mitsubishi Chemical (record owner of the '052 patent) and Encysive (holder of FDA approval to sell argatroban in the U.S.) that it had submitted ANDA No. 79-238 to the Food and Drug Administration with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '052 patent is invalid, unenforceable, or not infringed by the product of the ANDA. The submission of the ANDA with this "Paragraph IV certification" thus seeks approval to market a generic argatroban product before the expiration of the '052 patent. In response, on December 28, 2007, Mitsubishi Chemical, Mitsubishi Tanabe, Encysive, SKB, and SKB Corp. filed a Complaint against Barr for infringement of the '052 patent. The GSK Plaintiffs now admit – contrary to the allegations of the Complaint – that SKB Corp. was merely a ***non-exclusive licensee*** of the '052 patent at the time the Complaint was filed. (Motion at 2.)

On January 15, 2008, Barr Laboratories, Inc. sent an additional letter which informed Mitsubishi Chemical and Encysive that Barr had submitted ANDA No. 79-238 as agent

for Pliva-Hrvatska d.o.o. Barr answered the original Complaint on February 11, 2008. Barr consented to plaintiffs filing an amended complaint (the "First Amended Complaint") on February 21, 2008, in light of the January 15 letter. The First Amended Complaint was filed by Mitsubishi Chemical, Mitsubishi Tanabe, Encysive, SKB, and GGL against Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o. The First Amended Complaint rearranged the parties by (1) adding Pliva as a defendant, (2) dropping SKB Corp. as a plaintiff, and (3) adding GGL as a plaintiff. At that time, Barr was not advised of the reasons why SKB Corp. had been dropped and GGL added as a plaintiff. Subsequently, the GSK Plaintiffs admitted that the change was made because as of February 21, 2008, SKB Corp. was only a ***non-exclusive*** licensee while GGL allegedly was an ***exclusive*** licensee under the '052 patent. (Motion at 2.) Shortly thereafter, the GSK Plaintiffs changed course and decided to try to pump additional rights of exclusivity into SKB Corp. by amending an agreement between GGL and SKB Corp., and then sought to add SKB Corp. to this suit as a plaintiff.

Thus, on February 29, 2008, the GSK Plaintiffs filed the instant Motion to add SKB Corp. back in as a plaintiff because, allegedly, "the license agreement between SKB Corp. and GGL was amended to provide, among other things, that SKB Corp. is ***exclusive licensee*** of the patent-in-suit. SKB Corp., therefore, is now a proper party." (Motion at 2, emphasis added.)

III. LEAVE TO AMEND AGAIN SHOULD BE DENIED

When evaluating a motion for leave to amend, the Court should evaluate factors including "undue delay, bad faith or dilatory motive . . . repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Here,

the GSK Plaintiffs' Motion should be denied because (1) their proposed amendment is futile, (2) their proposed amendment will prejudice Barr, and (3) the GSK Plaintiffs failed to cure SKB's Corp.'s standing deficiency by previous amendment.

A. The GSK Plaintiffs' Motion Is Futile Because SKB Corp. Lacks Standing

An amendment is futile if it would not withstand a motion to dismiss. *Oneida Indian Nation of New York v. City of Sherill*, 337 F.3d 139, 168 (2d Cir. 2003) (denying motion to amend complaint), *rev'd on other grounds*, 544 U.S. 197 (2005). "Futility of amendment can, by itself, justify denial of a motion for leave to amend . . . ." *Bonin v. Calderone*, 59 F.3d 815, 845 (9th Cir. 1995). Since SKB Corp. lacks standing to participate as a plaintiff in this suit, the GSK Plaintiffs' Motion is futile and should be denied.

1. SKB Corp. Lacked Standing When The Complaint Was Filed

Standing is a threshold requirement. *Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 975 (Fed. Cir. 2005). Standing to sue for patent infringement is controlled by Article III of the Constitution and the Patent Act, 35 U.S.C. § 1 et seq. *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1338-39 (Fed. Cir. 2007). Constitutional standing requires that a plaintiff suffer an injury in fact that is causally connected to the defendant's conduct and is redressable by a favorable court decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Since the right to exclude is the legal interest created by the Patent Act, only a party holding exclusionary rights to the patent can suffer legal injury in fact. *Morrow*, 499 F.3d at 1339.

The Court of Appeals for the Federal Circuit has identified three categories of putative plaintiffs that are encountered when analyzing the constitutional standing issue in patent infringement suits: (1) those that can sue in their own name alone; (2) those that can sue as long as the patent owner is joined in the suit; and (3) those that cannot participate as a party to an

infringement suit. *Id.* at 1339-40.

The first category includes the patentee or assignee of all substantial rights in the patent. *Id.* at 1339. The second category includes a licensee, usually referred to as an "exclusive licensee," that holds exclusionary rights but not all substantial rights to the patent. *Id.* at 1340. An exclusive licensee ordinarily must join the patentee in the suit to satisfy prudential standing requirements, in particular to avoid the potential for multiple litigations and multiple liabilities and recoveries against the same alleged infringer. *Id.* at 1340.

The third category of putative plaintiffs is relevant to the GSK Plaintiffs' Motion. It includes a licensee that holds less than all substantial rights to the patent and lacks exclusionary rights under the Patent Act to meet the injury in fact requirement. *Id.* at 1340-41. Such a licensee – lacking exclusionary rights – is typically referred to as a "non-exclusive" or "bare" licensee. *See, e.g.*, *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552-53 (Fed. Cir. 1995) (en banc).

SKB Corp. had no standing when this lawsuit was instigated because it was – as the GSK Plaintiffs now admit – a non-exclusive licensee. (Motion at 2.) That standing deficiency could not be cured by joining SKB Corp. as a co-plaintiff with the patent owner in the suit. *Morrow*, 499 F.3d at 1341. Thus, it was proper and necessary for the GSK Plaintiffs to remove SKB Corp. as a party in the First Amended Complaint, even though the recorded patent owner, Mitsubishi Chemical, was also a named plaintiff.

2. SKB Corp.'s Standing Deficiency Cannot Be Cured Retroactively

Realizing that SKB Corp. lacked standing when suit was filed, the GSK Plaintiffs allegedly amended an agreement between GGL and SKB Corp. in recent days to transform SKB Corp. into an exclusive licensee. (Motion at 2.) However, this amendment cannot retroactively provide standing for SKB Corp. in this suit because a party must have standing to sue at the

inception of the lawsuit. *Lujan*, 504 U.S. at 570 n.5 ("[S]tanding is to be determined as of the commencement of the suit."); *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003) ("[T]his court has determined that in order to assert standing for patent infringement, the plaintiff must demonstrate that it held enforceable title to the patent *at the inception of the lawsuit*.") (emphasis in original).

A post-complaint amendment to a license agreement is ineffective to cure standing defects. The Federal Circuit has made clear that "*nunc pro tunc* assignments are not sufficient to confer retroactive standing . . . ." *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093-94 (Fed. Cir. 1998). The Federal Circuit explained that:

> As a general matter, ***parties should possess rights before seeking to have them vindicated in court***. Allowing a subsequent assignment to automatically cure a standing defect would unjustifiably expand the number of people who are statutorily authorized to sue. Parties could justify the premature initiation of an action by averring to the court that their standing through assignment is imminent. Permitting non-owners and licensees the right to sue, so long as they eventually obtain the rights they seek to have redressed, would enmesh the judiciary in abstract disputes, risk multiple litigation, and provide incentives for parties to obtain assignment in order to expand their arsenal and the scope of litigation. Inevitably, delay and expense would be the order of the day.

Id. at 1093-94 (citation omitted and emphasis added).

Given these principles, the Federal Circuit repeatedly has affirmed the dismissal of a complaint for lack of standing despite a purported *nunc pro tunc* license agreement. *See, e.g., Quiedan Co. v. Central Valley Builders Supply Co.*, No. C 92-3532 BAC, 1993 WL 451503, at *2 (N.D. Cal. Oct. 28, 1993), *aff'd*, 31 F.3d 1178 (Fed. Cir. 1994); *Afros S.p.A. v. Krauss-Maffei Corp.*, 671 F. Supp. 1402, 1445-46 (D. Del. 1987), *aff'd*, 848 F.2d 1244 (Fed. Cir. 1988).

Indeed, the Federal Circuit has vacated a final judgment of patent infringement after a jury trial on the merits because of a standing deficiency, despite the existence of a *nunc*

pro tunc assignment of the patent-in-suit to the named plaintiff. *Gaia Techs., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774, 779 (Fed. Cir. 1996) ("The only possible saving grace for Gaia is the *nunc pro tunc* assignment of patent and trademark rights that was executed on October 24, 1994, but was made effective as of August 4, 1991, prior to Gaia's filing of the instant suit. . . . This agreement is not sufficient to confer standing on Gaia retroactively.") *See also Multistack LLC v. ArcticHill Inc.*, No. 05-CIV-3865 (PAC), 2006 WL 510506, at *4 (S.D.N.Y. Mar. 1, 2006) (dismissing case with prejudice; *nunc pro tunc* assignment from patentee did not confer retroactive standing, and joinder of patentee did not cure standing defect because patentee later relinquished all rights to the patent). *Cf. Paradise Creations*, 315 F.3d at 1310 (affirming dismissal due to lack of standing where corporation was administratively dissolved when complaint was filed; reinstatement of corporation could not vest enforceable title to the patent retroactively).

Because a standing deficiency can taint an entire case, "[i]t is prudent to resolve standing issues in the early stages of litigation to avoid what might be unnecessary efforts by the parties and the court." *Galen Med. Assoc., Inc. v. United States*, 74 Fed. Cl. 377, 379 (Ct. Cl. 2006). One district court noted the importance of addressing standing issues early on so that litigation can proceed efficiently. "District judges cannot overlook a defect in the chain of title, for the entirety of massive litigation might wind up being vacated years later, for lack of threshold standing." *Quantum Corp. v. Riverbed Tech.*, No. C-07-04161, 2008 WL 314490, at *3 (N.D. Cal. Feb. 4, 2008).

3. There Is No Applicable Exception Here To The General Rule That Standing Cannot Be Cured Retroactively

Courts have recognized two narrow exceptions to the general rule that parties must have and maintain standing throughout a case, and neither of them apply to SKB Corp.

First, parties that have Article III standing when a complaint is filed, but who lose standing during the case, may in some instances cure a standing defect before judgment. *See Schreiber Foods Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198 (Fed. Cir. 2005). That exception does not apply here because SKB. Corp. did not have standing when the Complaint was filed.

Second, an exclusive licensee with Article III standing that attempts to sue in its own name may be allowed to retroactively cure prudential standing defects by adding the patent owner. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016, 1018 (Fed. Cir. 2001). That exception does not apply here because SKB Corp. was a non-exclusive licensee with no Article III standing at the time the Complaint was filed. *See Hako-Med USA, Inc. v. Axiom Worldwide, Inc.*, No. 8:06-CV-1790-T-27EAJ, 2006 WL 3755328, at *5 n.5 (M.D. Fla. Nov. 15, 2006) ("*If the original plaintiff lacks constitutional standing, the suit must be dismissed*, but if the original plaintiff had constitutional standing, any prudential standing concerns may be overcome by adding a plaintiff with proper standing.") (emphasis added).

Since non-exclusive licensees lack constitutional standing, they cannot cure standing defects by adding a proper party. *See, e.g., Merial Ltd. v. Intervet Inc.*, 430 F. Supp.2d 1357, 1363-64 (N.D. Ga. 2006) (granting motion to dismiss; non-exclusive licensee not allowed to cure standing defect by adding a party with standing). Here, SKB Corp. lacked constitutional standing when the Complaint was filed. It cannot cure its standing deficiency retroactively, and no exception applies.

B. The GSK Plaintiffs' Proposed Amendment Would Prejudice Barr

The GSK Plaintiffs recognize that a party may not amend pleadings if there is "a showing by the nonmovant of prejudice or bad faith." *Block v. First Blood Assocs.*, 988 F.2d

344, 350 (2d Cir. 1993). Here, the GSK Plaintiffs' proposed amendment would prejudice Barr because the presence of SKB Corp. likely would impact the evaluation of any request for injunctive relief and possible damages if the patent-in-suit eventually were not invalidated.

1. Adding SKB Corp. Would Prejudice Barr

Section 271(e)(4) of the Patent Act sets forth the remedies available in a litigation brought under Section 271(e)(2), including (1) injunctive relief to prevent the use, sale, offer to sell, or importation of an approved generic product and (2) damages if there has been a commercial manufacture, use, offer to sell, sale, or importation of the approved product. 35 U.S.C. § 271(e)(4)(B) and (C) (2008). If this lawsuit were not resolved before the FDA approves the argatroban ANDA, it is possible that the plaintiffs could seek injunctive relief against generic argatroban sales and Barr could choose to sell its product if injunctive relief were not granted. In many cases involving generic drug applications, the courts have denied injunctive relief and ultimately have found no liability upon which a damages award could rest. However, Barr must assume that plaintiffs will eventually press these issues and that it would be required to meet any such arguments. Thus, the Court may need to address the issues of injunctive relief and potential damages in this litigation.

SKB Corp.'s addition to this case almost certainly would affect the calculus on these issues. A patentee or exclusive licensee is not presumptively entitled to a permanent injunction, but must prove "(1) that it suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy at equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (U.S. 2006). A party seeking preliminary injunctive relief must establish four similar factors: "(1) a reasonable likelihood of its success on

the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's . . . impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). In either context, the party seeking injunctive relief must show irreparable harm.[1]

Here, the plaintiffs cannot base their request for injunctive relief on alleged losses by SKB Corp. Any alleged injury to SKB Corp. could not be imputed to SKB, GGL, or any other plaintiff. *eBay*, 547 U.S. at 391 ("A *plaintiff* must demonstrate: (1) that *it has suffered an irreparable injury*") (emphasis added). Although SKB and GGL *may* have standing to sue and seek injunctive relief, they cannot base any request for injunctive relief on supposed harm to a non-party. *Am. Dairy Queen Corp. v. Brown-Port Co.*, 621 F.2d 255, 257-58 (7th Cir. 1980) ("Merely because the [plaintiff] has standing to sue does not mean that recovery or injunctive relief can be based on actual or potential injury to . . . a *non-party*") (emphasis added); *Kirsner v. Johnson & Johnson Prods., Inc.*, 455 N.E.2d 292, 293 (Ill. App. 1983) (reversing preliminary injunction that "does not protect any rights of . . . potential plaintiffs, but only those of nonparties"). According to the GSK Plaintiffs' Motion, SKB Corp. "is the entity that sells Argatroban Injection in the United States." (Motion at 3.) Thus, although it is far from clear that

---

[1] There is some disagreement among district courts whether there is ever a presumption of irreparable harm post-*eBay*. *See, e.g., Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-CV-1887 (DMC), 2007 U.S. Dist. LEXIS 65792, at *1 (D.N.J. Sept. 6, 2007) (discussing disagreement among courts; denying preliminary injunction against generic company in ANDA case after applying *eBay* factors and finding that plaintiff was not entitled to a presumption of irreparable harm). The Federal Circuit has not yet clarified the issue. *See, e.g., Amado v. Microsoft Corp.*, No. 03-CV-242, 2008 U.S. App. LEXIS 4065, at *1 (Fed. Cir. Feb. 26, 2008) (declining to address the issue because the district court properly concluded there was an absence of irreparable harm); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (declining to address the issue because the district court found several kinds of irreparable harm).

SKB Corp. could allege any cognizable irreparable harm if it were a party, its presence in the case would present a different analysis. If SKB Corp. were added to the case, Barr could be prejudiced in an evaluation of injunctive relief.

Likewise, any assessment of damages could be affected by the presence of SKB Corp. as a party. The currently named plaintiffs would have no claim to lost profits because a party that does not sell the product in question is not entitled to lost profits. While "[i]t is true that the recovery of lost profits by a patentee is not limited to the situation in which the patentee is selling the patented device. . . . *the patentee needs to have been selling some item*, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits." *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (emphasis added); *see also Rite-Hite*, 56 F.3d at 1548 ("Normally, if the patentee is not selling a product, by definition there can be no lost profits.") Further, GGL and SKB could not collect lost profits on behalf of SKB Corp., even if they are parent or sister corporations. *See, e.g., Depuy, Inc. v. Zimmer Holdings, Inc.*, 384 F. Supp. 2d 1237, 1238-41 (N.D. Ill. 2005) (Posner, J.) (parent corporation lacked standing to seek lost profits on behalf of its subsidiary); *Poly-America*, 383 F.3d at 1310 (patentee could not recover lost profits on behalf of sister corporation).

2. The GSK Plaintiffs Should Be Held To Account For Their Strategic Choices

The GSK Plaintiffs may allege that they would be prejudiced if they cannot add SKB Corp. as a party since the plaintiffs' ability to seek injunctive relief or lost profits in this suit could be adversely affected. However, such pleas should not be countenanced. The GSK Plaintiffs are sophisticated corporate entities that should be forced to deal with the repercussions of their strategic choices. Such companies must deal with both the positive and negative

consequences of their corporate arrangements:

> Their parent has arranged their corporate identities and functions to suit its own goals and purposes, but it must take the benefits with the burdens. While we do not speculate concerning the benefits that the two companies reap from dividing their operations and separating the owner of the patent from the seller of the patented product, ***Poly-America and Poly-Flex may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure--in this case, the inability of the patent holder to claim the lost profits of its non-exclusive licensee***. While Poly-America may have the right to sue under its patents, both as an owner and as a back-licensee, it can recover only its own lost profits, not Poly-Flex's.

Poly-America, 383 F.3d at 1311 (emphasis added).

The same is true of GGL, SKB, and SKB Corp. – they may not enjoy the benefits of their corporate structure without bearing the burdens. In future cases, the GSK Plaintiffs may choose to address contractual arrangements among their corporate affiliates differently, but it is too late for them to do so in this case.

The plaintiffs conceivably could seek to dismiss this case and file a new one which might include SKB Corp. as a proper plaintiff if it had standing as of the inception of that suit. Plainly, they do not wish to do so since dismissal of this suit would eliminate their ability to maintain a 30-month regulatory stay of approval against the argatroban ANDA.[2] That is a strategic choice which plaintiffs must make, and it flows directly from their own actions.

---

[2] If an infringement suit is brought within 45 days of receipt of notice of an ANDA filing containing a Paragraph IV certification, then the FDA will not approve the ANDA for a period of 30 months, absent certain conditions being met such as successful resolution of the patent suit by the ANDA filer before that time. A new suit here would be outside the 45-day period.

C. The GSK Plaintiffs Failed To Cure Deficiencies By Prior Amendment

Courts should also consider "[r]epeated failure to cure deficiencies by amendments previously allowed" in determining whether to grant a motion to amend a complaint. *Foman*, 371 U.S. at 182 (1962). Here, the GSK Plaintiffs already filed a First Amended Complaint. At that time, the GSK Plaintiffs knew that SKB Corp. lacked standing – that is why they dropped SKB Corp. and added GGL as a party. (Motion at 2.)

Hence, despite having ample time to do so, despite knowing there were standing issues, and despite substantial delay, the GSK Plaintiffs chose not to cure the standing deficiencies of SKB Corp. in their first amendment but rather to drop them as a plaintiff. Even if the GSK Plaintiffs could have retroactively cured those standing deficiencies – which precedent teaches was not possible – they should not be allowed a third bite at the apple. As one district court has explained, standing is not so difficult to obtain at the outset as to freely warrant retroactive repair:

> In light of the proliferation of patent-infringement actions, ***it is not too much to ask sophisticated patent litigants to be careful when it comes to the threshold issue of standing***. It is a simple task to execute express license agreements that satisfy the Federal Circuit standard. Among affiliated companies, it should be even simpler. . . . As carpenters say, it is wise to "measure twice and cut once."

Quantum Corp., No. C-07-04161, 2008 WL 314490, at *3. (citation omitted and emphasis added). In this case, GSK Plaintiffs had the time, motive, and opportunity to undertake the "simple task" of executing an express exclusive license agreement before suing and then amending their Complaint. They chose not to do so, and now must deal with the consequences of their actions. Their Motion to amend again should be denied.

IV. CONCLUSION

For the foregoing reasons, the GSK Plaintiffs' Motion for Leave to File a Second Amended Complaint should be denied.

Date: March 17, 2008

s/ Thomas J. Meloro
Thomas J. Meloro, Esq.
Diane C. Ragosa, Esq.
Heather M. Schneider, Esq.
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019-6099
(212) 728-8000 Telephone
(212) 728-8111 Facsimile
TMeloro@willkie.com

Attorneys for Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o.